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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,264

05/11/2001

Susan M. Garthwaite

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8255

7590

09/10/2004

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/854,264	<b>Applicant(s)</b> GARTHWAITE ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23 and 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1615

## **DETAILED ACTION**

### **Status of the Application**

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114, Applicant's Arguments/Remarks and the request for extension of time (3 months-granted), all filed 05/11/04 is acknowledged.

Claims 23 and 25-27 are pending. Claim 23 has been amended. Claim 24 has been cancelled. Claims 23 and 25-27 are rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 23 and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devane *et al.* (US Pat. No. 6,228,398; hereafter '398) in view of Grob *et al.* (US 4,559,332; hereafter '332) and further in view of Jao *et al.* (US 5,160,744; hereafter '744) OR Faour *et al.* (US 6,569,456; hereafter '456) in view of Grob *et al.* (US 4,559,332; hereafter '332) and further in view of Jao *et al.* (US 5,160,744; hereafter '744).**

Devane *et al.* ('398) and Faour *et al.* ('456) teach controlled release anti-hypertension combination formulations that provide both immediate release and controlled release of the active agents. Neither reference teaches that the anti-hypertensive agent is an aldosterone antagonist or release of the active agent in accordance with the diurnal cycle of plasma aldosterone concentration.

Grob *et al.* ('332) teach aldosterone antagonists as potassium-saving diuretics for treatment of hypertension (see reference column 3, lines 38-47). Grob *et al.* do not teach the combination of the aldosterone antagonist with a second formulation having a second anti-hypertensive agent.

Jao *et al.* ('744) teach the administration of delayed release anti-hypertensive agents at bedtime to block the early morning rise of blood pressure (see Example 1). Jao *et al.* teach the inclusion of active drugs, such as antihypertensive agents, cardiovascular drugs, calcium channel inhibitors, diuretics, sympathomimetics, angiotensin converting enzyme (ACE) inhibitors and the like (col. 7, lines 10-26).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to provide an anti-hypertensive formulation having two anti-hypertensive agents where the formulation releases one of the agents in accordance with the early morning rise of blood pressure and one of the agents is an aldosterone antagonist with the motivation that substitution of an aldosterone antagonist for one of the anti-hypertensive agents of either Devane *et al.* ('398) or Faour *et al.* ('456) would result in the same effect (i.e., reduction of hypertension) while sparing potassium and avoiding the early morning rise of blood pressure.

In summary, there is no significant distinction observed between the instant invention and the prior art, since the prior art teaches aldosterone antagonists and anti-hypertensive combination formulations in distinct release forms comprising aldosterone antagonist drugs, such as eplerenone for the effective treatment of hypertension. Therefore, the instant invention as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made. Thus, the instant invention is rendered *prima facie* obvious over the cited prior art of record.

### ***Response to Arguments***

Applicant's arguments filed 05/11/04 have been fully considered but they are not persuasive.

Applicant argued, "The references, even if combined in the manner suggested by the Office, would not provide the claimed invention. The references would not provide a

Art Unit: 1615

composition in which the aldosterone antagonist drug is selected from eplerenone and spironolactone, and the second antihypertensive agent is selected from a diuretic, a sympatholytic agent, an ACE inhibitor, a vasopectidase, a calcium channel blocker, a direct vasodilator, a renin inhibitor and an angiotensin II antagonist.”

This argument has been fully considered, but was not found to be persuasive. The prior art expressly teaches aldosterone antagonists and anti-hypertensive combination formulations in distinct release forms comprising aldosterone antagonist drugs, such as eplerenone, for the effective treatment of hypertension. The Jao ('744) patent was relied upon for the additional teaching of suitable active drugs for use in the formulation that include among others, antihypertensive agents, cardiovascular drugs, calcium channel inhibitors, diuretics, sympathomimetics, angiotensin converting enzyme (ACE) inhibitors and the like (col. 7, lines 10-26). Therefore, it is the position of the Examiner, that the instant invention is rendered *prima facie* obvious over the instant invention.

### Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

Art Unit: 1615

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

H. N. Sheikh *H.N.S.*

Patent Examiner

Art Unit 1615

September 01, 2004

*[Signature]*  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1800